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(54) Abstract Title
Deposition of a chemical solution on a test device using a printer

(57) A method for depositing a chemical in solution on a test device 10 of testing apparatus for testing a fluid medium comprises the step of depositing the chemical from a printer apparatus on to the test device. The printer apparatus may be of the inkjet type, the bubblejet type or the piezo-electric jet type. A plurality of nozzles of the printer are preferably used to simultaneously control the position of the plurality of droplets onto the test device, the nozzle depositing the droplets in a predetermined pattern of dots. A plurality of different chemical solutions can be deposited on the test device via a plurality of nozzles and the different chemicals may be mixed with different coloured inks.

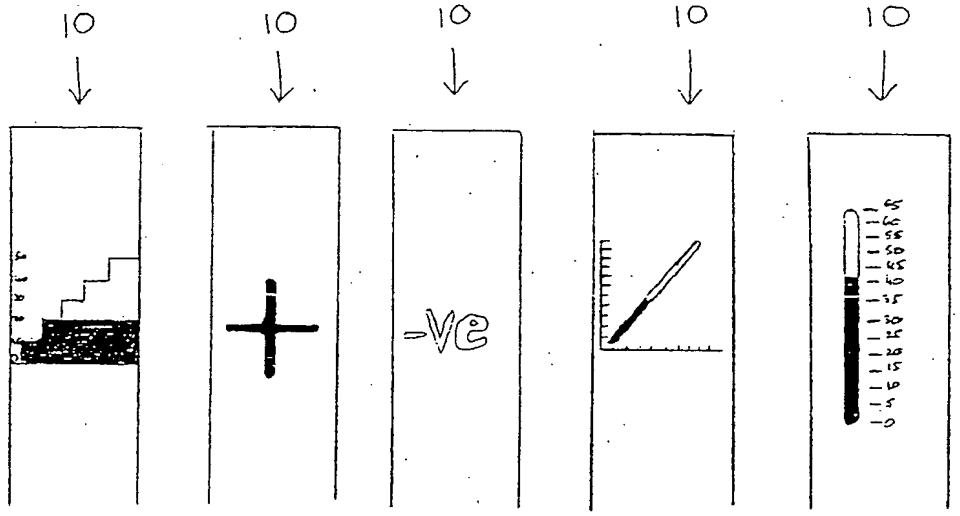

FIG 2a FIG 2b FIG 3c FIG 2d FIG 2e

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date but within the period prescribed by [illegible]

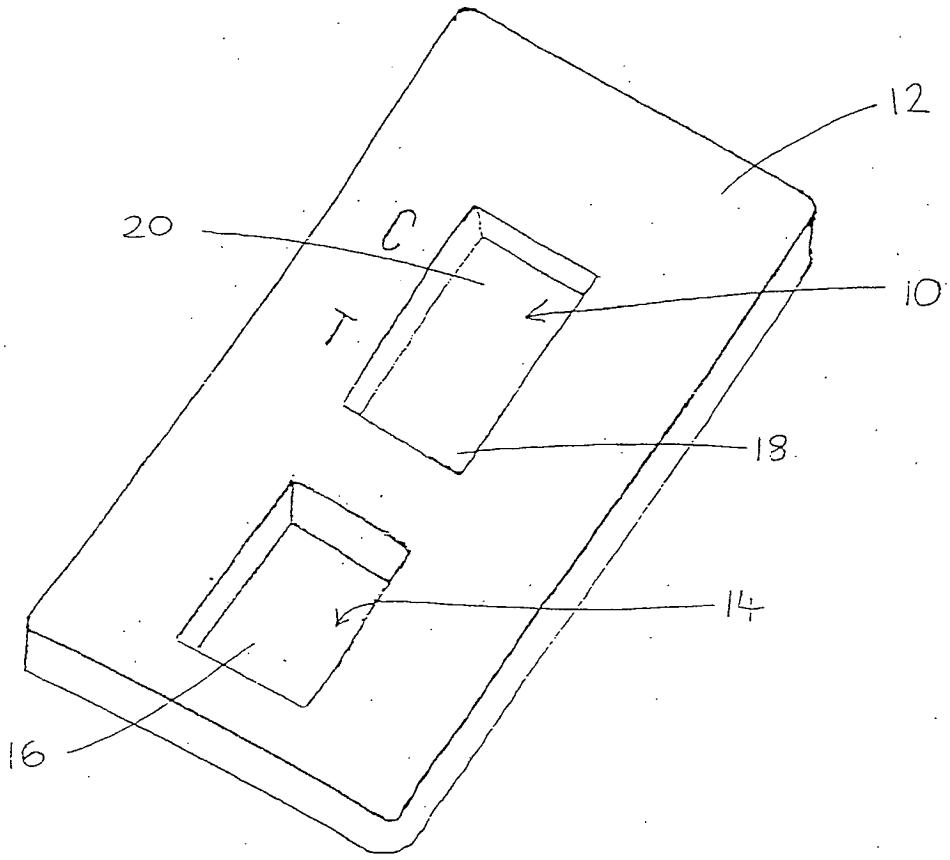


FIG 1

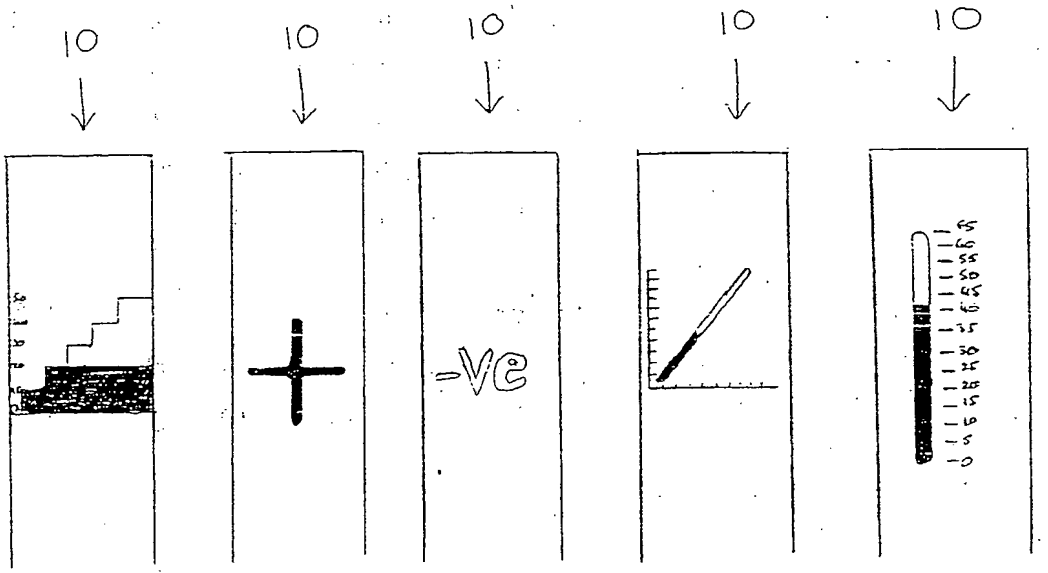
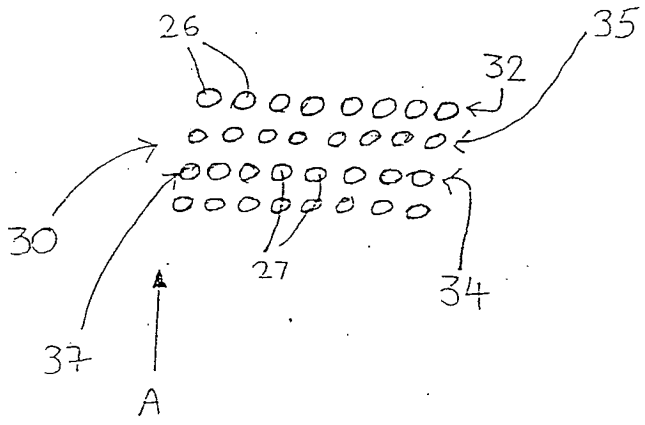


FIG 2a FIG 2b FIG 3c FIG 2d FIG 2e

FIG. 3



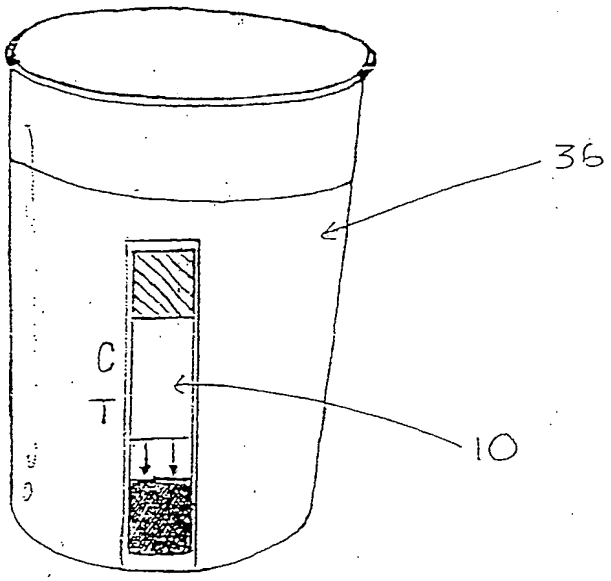


FIG 4

Testing Apparatus

This invention relates to testing apparatus for testing fluids. A particular application of the invention is in testing urine samples for the presence of drugs.

Most drug screening uses lateral flow immunoassay test technology in which a sample of fluid to be tested passes along a lateral flow membrane and reacts with chemicals, such as antibodies, to test for the presence of a drug or other substance in the sample. The membrane is usually provided on a plastics strip and one or more strips may be mounted on or within a housing to form a testing apparatus. In use, the testing apparatus may be dipped into the sample to be tested or a small amount of the sample to be tested may be dropped onto the testing apparatus using a pipette.

Conventionally the chemicals which test for the presence of drugs in the sample are deposited on the membrane by mechanical means. Common methods include depositing the chemical in solution from a pump, through a flexible tube.

The volume of solution (and thus the amount of chemical) which is deposited on the membrane depends then upon a variety of factors including:

- the viscosity of the solution;
- the temperature of the solution;
- the rate of pumping of the solution;
- the dimensions of the tube, including the shape of its nozzle; and
- the absorbency of the membrane.

Since there are a large number of factors affecting the quantity of the chemicals deposited on each membrane, there can be potentially significant variations in the amount of chemical present between different membranes. In fact significant variations can also be found between different areas on a single membrane.

Therefore presently it is difficult to obtain tests which provide accurate information on the quantity of a substance being tested for in a sample. Present tests are qualitative, only being able to indicate whether the concentration of a substance within a sample is above or below a predetermined limit. However, it is useful to be able to perform a quantitative test, which provides an indication of the concentration in the sample of the substance being tested for. Such quantitative tests can distinguish, when testing for the presence of illegal drugs in a urine sample for example, whether a positive test is obtained from a casual user of the drug or a serious addict.

According to the present invention there is provided a method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method comprising depositing the chemical from a printer apparatus onto the test device.

The printer apparatus may be of the inkjet type.

The printer apparatus may be of the bubblejet type.

The printer apparatus may be of the piezo-electric jet type.

According to a further aspect of the invention there is provided a method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method including the steps of:

placing the chemical solution in a nozzle;

heating the chemical solution in the nozzle to form a bubble in the nozzle causing a droplet of chemical solution to be ejected from the nozzle and deposited on the test device.

Preferably the chemical solution is heated by a heating element provided in the nozzle. Most preferably the chemical solution is heated for a predetermined time. Preferably the bubble is formed on the heating element.

Preferably the nozzle is attached to a reservoir containing the chemical

solution. Preferably as the chemical solution cools in the nozzle following ejection of a droplet of chemical solution, the bubble deflates and draws chemical solution from the reservoir, to refill the nozzle.

According to a further aspect of the invention there is provided a method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method including the steps of:

placing the chemical solution in a nozzle;

vibrating the chemical solution in the nozzle to cause a droplet of the chemical solution to be ejected from the nozzle and deposited on the test device.

Preferably a piezo-electric material provided in the nozzle is caused to vibrate by passing an electric current therethrough causing a droplet of the chemical solution in the nozzle to be ejected from the nozzle. Preferably the piezo-electric material is vibrated for a predetermined time.

Preferably the nozzle is attached to a reservoir containing the chemical solution. Preferably, when the piezo-electric material vibrates in a first direction, a droplet is ejected from the nozzle, and when the piezo-electric material vibrates in the opposite direction, chemical solution is drawn from the reservoir into the nozzle.

According to the invention there is further provided a method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method comprising the steps of:

magnetising, polarising or electrically charging the chemical solution, ejecting a droplet of the chemical solution from a nozzle along a path towards the test device, and selectively applying an electrical field in the region of the path to control the path of movement of the droplet of chemical solution.

The electrical field may be an electrostatic field.

Preferably the chemical is initially directed on a path towards a predetermined location on the device, and the electrical field is controlled to allow or prevent the chemical reaching that location.

Preferably the electrical field is able to deflect droplets such that said droplets do not reach the test device.

Preferably the electrical field is established by a charged vane. Preferably the droplets that do not reach the test device are re-directed onto a collection member.

The chemical solution may be magnetised by mixing it with a magnetising agent, in solution. . The magnetising agent may be in the form of colloidal iron particles or iron spheres. Alternatively, the chemical solution may be mixed with a polar solvent, for example, an alcohol or water.

In each of the above embodiments, preferably a plurality of nozzles are utilised to simultaneously control the deposition of a plurality of droplets onto the test device. Preferably the nozzles deposit the droplets in a predetermined pattern of dots. The pattern may comprise a line of dots having a density of between 5 and 25 dots per millimetre. Most preferably the line density is about 10 to 15 dots per millimetre.

Alternatively the pattern comprises an array of dots. The line density of the array may be between 5 and 25 dots per millimetre, most preferably 10 to 15 dots per millimetre. The array may be a rectangular array of dots.

The density of the dots may vary across the pattern.

A plurality of different chemical solutions may be deposited on the test device via a plurality of nozzles. Different concentrations of the same chemical may be deposited in solution on the device through different nozzles.

The chemicals may be mixed with coloured inks, which could be

respectively different colours for the different chemicals.

According to the invention there is also provided testing apparatus for testing a fluid medium, the apparatus including a test device for providing an indication as to the presence of a selected substance within the medium, including a chemical deposited on the device in a predetermined pattern, using a method according to any of the previous definitions.

Preferably the pattern comprises a plurality of dots. The pattern may comprise a line of dots having a density of between 5 and 25 dots per millimetre, most preferably 10 to 15 dots per millimetre. Alternatively the pattern may comprise an array of dots, preferably having a density of between 5 and 25 dots per millimetre, most preferably 10 to 15 dots per millimetre.

The density of the dots may vary across the pattern.

A plurality of chemicals may be deposited on the test device. Different dots may contain respectively different concentrations of the same chemical. A first chemical may comprise an antibody to detect the selected substance, a second chemical may comprise a dye.

A plurality of antibodies may be provided. Each antibody may be located on a distinct region of the test device and each may indicate the presence of a different selected substance.

The test device preferably provides provide an indication of the concentration of the selected substance within the fluid medium.

The test device may include a lateral flow membrane and may be in the form of a test strip.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic illustration of a testing apparatus according to a first embodiment of the invention;

Figs 2a,b,c,d,e are diagrammatic illustrations of test strips to be used with the testing apparatus of Fig. 1;

Fig. 3 illustrates diagrammatically a pattern of chemicals deposited on a test device according to the invention; and

Fig. 4 is a diagrammatic illustration of testing apparatus according to a second embodiment of the invention.

Referring to Fig. 1, there is illustrated a testing apparatus in the form of a test strip 10 located in a housing 12. The test strip 10 includes a lateral flow membrane and is suitable for testing for substances in fluid samples, for example drugs in urine samples.

The housing 12 includes an opening in the form of a well 14, in which a sample receiving portion 16 of the strip 10 is exposed.

When a sample to be tested is dropped, by pipette for example, into the well 14 and onto the sample receiving portion 16, it travels along the lateral flow membrane by capillary action to a test portion 18. At the test portion 18, test chemicals on the strip 10 may react with the sample to indicate the presence of selected substances within the sample. The results of the test are indicated at a results viewing portion 20 by a colour change as the reaction occurs. This process is known.

The Applicant has realised that in order to provide accurate quantitative tests (i.e. to indicate the concentration of a selected substance in a sample, as well as indicating its presence or absence), the deposition of test chemicals at the test portion 18 must be accurately controlled.

In order to achieve this, the test chemical is deposited through a printer apparatus, such as a bubblejet printer, a piezo-electric jet printer or an electrostatic printer onto the test strip 10. The test chemical is loaded into an empty ink cartridge and the printer is then operated as normal.

The printer includes a series of nozzles, each nozzle being capable of releasing a droplet 22 of the test chemical onto the test strip 10. A computer program is used to determine which nozzles are activated during each print run and therefore the program determines the resulting pattern of dots on the test strip 10. Each droplet 22 contacts the test strip and forms a dot. The line density of the dots is typically 10 to 15 dots per millimetre and is known very precisely. The amount of chemical in each droplet is also known very precisely and therefore accurate, known amounts of test chemical are deposited on the strip 10.

In a bubblejet printer, the chemical solution to be deposited on the test strip 10 is ejected from the nozzle by heating it rapidly such that it vaporises to form a bubble. Expansion of the bubble ejects the droplet from the nozzle in a controlled manner. The solution is then allowed to cool, and its resulting contraction draws more solution into the nozzle from an adjacent reservoir. This is known technology.

A piezo-electric printer operates in a similar manner to the above except that the ejection is caused by displacing a piezo-electric crystal by passing current therethrough. This is also know technology.

In another embodiment, a solution of test chemical is initially magnetised. This can be done by mixing it with colloidal iron particles or iron spheres for example. Alternatively, the test chemical may be charged by dissolving it in a polar solvent, such as an alcohol or water. The particular form of magnetisation or charging of the test chemical depends upon the test chemical itself, which in turn is determined by the substance being tested for.

A coloured ink may also be added to the test chemical solution in order to give a visual indication that the test chemical is being applied as required (i.e. at a constant density for example) to the strip 10.

Once the test chemical has been magnetised or charged, a droplet 22 of the chemical solution is sprayed towards the strip 10 from a nozzle. The droplet 22 of the test chemical passes through an electrostatic field established by charged vanes 24.

In each of the above embodiments, the pattern of dots on the test strip 10 (caused by droplets of ink) is determined by a computer program controlling the movement of the nozzles and the heating to cause bubbles, activation of the piezo-electric crystal or operation of the charged vanes 24 depending upon the printer used.

Figs. 2a to e show five examples of patterns formed on test strips 10 using the method of the present invention.

Figs. 2b and c show qualitative tests for indicating only the presence or absence of a substance in a sample being tested. By using the method of deposition on the invention, the tests can be made very reliable.

Figs. 2a, d and e show tests in which the concentration of the test chemical is varied along the length of the strip 10 to provide a quantitative test. In the illustrated examples, a higher density of test chemical is deposited on the bottom of the strip compared to the top. Thus a low concentration of drug, for example, in the sample will cause the bottom region of the strip to change colour and the top region to remain unchanged. The results can therefore be read against a scale which is pre-calibrated according to the precise amount of test chemical at each point on the strip.

The concentration of test chemical deposited on the test strip 10 may be varied in a number of ways. Firstly the density of the dots can be varied, so that

each dot contains the same amount of test chemical but there are more dots on one part of the test strip 10 than another.

An alternative is to provide different concentrations of the test chemical. In this way both the amount of test chemical in each dot and also the density of the dots may be varied.

In conventional test strips, a dye is provided at one end of a membrane, upstream of the test region of the membrane. A sample dropped onto the sample receiving portion, upstream of the dye, travels across the membrane and mixes with the dye before passing over the test chemical. The reaction with the test chemical occurs, then the excess sample passes by with the dye.

The test result is obtained and read once the excess sample has washed away the excess dye. The method of the present invention improves this by:

- depositing the dye more accurately so that the dye clears more quickly from the test;
- allowing the dye and test chemical to be deposited in the same region as an array 30 of dots, which means the transport distance between the dye and chemical is minimised making the test very quick. An example of this is shown in Fig. 3;

The Applicant has also provided a method in which the resulting testing apparatus requires a minimal amount of sample to be tested to be applied to make the test work. This is particularly useful in situations such as blood based medical testing.

Fig. 3 illustrates how two different substances may be tested for by depositing different chemicals in the same region. In this example, the dots 26 of row 32 contain an antibody for THC (cannabis) and the dots 27 of row 34 contain an antibody for an STD (sexually transmitted disease). Rows 35 and 37 consist of dots containing the conjugate for the THC test and the STD test respectively. Fluid flows in the direction of the arrow A. The dots are kept

quite separate. This is advantageous over prior methods in which only certain compatible test chemicals could be deposited on the same strip in the same region.

Various modifications may be made without departing from the scope of the present invention. For example, the test device may be applied to any testing apparatus. Fig. 4 shows the strip 10 incorporated into a testing cup 36 in which the sample to be tested is simply provided in the cup.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

CLAIMS

1. A method of depositing a chemical solution on a test device of a testing apparatus for testing a fluid medium, the method comprising depositing the chemical from a printer apparatus onto the test device.

2. A method according to claim 1 wherein the printer apparatus is of the inkjet type.

3. A method according to claim 1 wherein the printer apparatus is of the bubblejet type.

4. A method according to claim 1 wherein the printer apparatus is of the piezo-electric jet type.

5. A method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method including the steps of:

placing the chemical solution in a nozzle;

heating the chemical solution in the nozzle to form a bubble in the nozzle causing a droplet of chemical solution to be ejected from the nozzle and deposited on the test device.

6. A method according to claim 5 wherein the chemical solution is heated by a heating element provided in the nozzle, for a predetermined time.

7. A method according to claim 6 wherein the bubble is formed on the heating element.

8. A method according to any of claims 5 to 7 wherein the nozzle is attached to a reservoir containing the chemical solution, and as the chemical solution cools in the nozzle following ejection of a droplet of chemical solution, the bubble deflates and draws chemical solution from the reservoir, to refill the nozzle.

9. A method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method including the steps of:

placing the chemical solution in a nozzle;

vibrating the chemical solution in the nozzle to cause a droplet of the chemical solution to be ejected from the nozzle and deposited on the test device.

10. A method according to claim 9 wherein a piezo-electric material provided in the nozzle is caused to vibrate by passing an electric current therethrough causing a droplet of the chemical solution in the nozzle to be ejected from the nozzle, the piezo-electric material being vibrated for a predetermined time.

11. A method according to claim 9 or claim 10 wherein the nozzle is attached to a reservoir containing the chemical solution, and when the piezo-electric material vibrates in a first direction, a droplet is ejected from the nozzle, and when the piezo-electric material vibrates in the opposite direction, chemical solution is drawn from the reservoir into the nozzle.

12. A method of depositing a chemical in solution on a test device of a testing apparatus for testing a fluid medium, the method comprising the steps of:

magnetising, polarising or electrically charging the chemical solution;

ejecting a droplet of the chemical solution from a nozzle along a path towards the test device; and

selectively applying an electrical field in the region of the path to control the path of movement of the droplet of chemical solution.

13. A method according to claim 12 wherein the electrical field is an electrostatic field.

14. A method according to claim 13 wherein the chemical is initially directed on a path towards a predetermined location on the device, and the electrical field is controlled to allow or prevent the chemical reaching that location, the electrical field being able to deflect droplets such that said droplets do not reach the test

device.

15. A method according to claim 14 wherein the electrical field is established by a charged vane and the droplets that do not reach the test device are re-directed onto a collection member.

16. A method according to any preceding claim wherein a plurality of nozzles are utilised to simultaneously control the deposition of a plurality of droplets onto the test device, the nozzles depositing the droplets in a predetermined pattern of dots.

17. A method according to claim 16 wherein the pattern comprises a line of dots having a density of between 5 and 25 dots per millimetre.

18. A method according to claim 16 wherein the pattern comprises an array of dots, the line density of the array being between 5 and 25 dots per millimetre.

19. A method according to any of claims 16 to 18 wherein a plurality of different chemical solutions are deposited on the test device via a plurality of nozzles or different concentrations of the same chemical are deposited in solution on the device through different nozzles.

20. A method according to claim 19 wherein the chemicals are mixed with coloured inks, which are respectively different colours for the different chemicals.

21. Testing apparatus for testing a fluid medium, the apparatus including a test device for providing an indication as to the presence of a selected substance within the medium, including a chemical deposited on the device in a predetermined pattern, using a method according to any preceding claim.

22. Apparatus according to claim 21 wherein the pattern comprises a plurality of dots having a density of between 5 and 25 dots per millimetre.

23. Apparatus according to claim 22 wherein the density of the dots varies across the pattern.

24. Apparatus according to any of claims 21 to 23 wherein a plurality of chemicals are deposited on the test device, a first chemical comprising an antibody to detect the selected substance and a second chemical comprising a dye.

25. Apparatus according to claim 24 wherein a plurality of antibodies are provided, each antibody being located on a distinct region of the test device and each indicating the presence of a different selected substance.

26. Apparatus according to any of claims 21 to 25 wherein the test device provides provide an indication of the concentration of the selected substance within the fluid medium.

27. Apparatus according to any of claims 21 to 26 wherein the test device includes a lateral flow membrane.

28. A method substantially as herein described with reference to the drawings.

29. Apparatus substantially as herein described with reference to the drawings.

31. Any novel subject matter or combination including novel subject matter disclosed herein, whether or not within the scope of or relating to the same invention as any of the preceding claims.

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Application No: GB 0205375.9 **Examiner:** Signe Gravsholt
Claims searched: all **Date of search:** 8 July 2003.

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1,2,16, 19,21, 23-31	CH 0692 008 A5	(GYOGYNOEVENY RT KI) See WPI Abstract Acc. No. 2002-098319/14
A		WO 01/04614 A1	(WAKUNGA PHARMACEUTICAL CO0 See WPI Abstract Acc.No. 2001-138386/14

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[V]:

Worldwide search of patent documents classified in the following areas of the IPC[7]:

G01N

The following online and other databases have been used in the preparation of this search report:

Online: EPODOC, JAPIO, NPL, INSPEC, MEDLINE